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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-2335]

Medical Gloves; Draft Guidance Manual; Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to January 27, 2000, the comment period for the draft guidance entitled "Medical Glove Guidance Manual." FDA published a notice of availability of the draft guidance in the **Federal Register** of July 30, 1999 (64 FR 41744). The agency is taking this action to harmonize the comment period for the draft guidance with the extension of the comment period for the proposed rule on the reclassification of surgeon's and patient examination gloves (64 FR 41710, July 30, 1999). The document announcing the extension of that comment period for the proposed rule is published elsewhere in this issue of the **Federal Register**. The draft guidance is a proposed special control for that reclassification. This extension of the comment period is intended to allow interested persons additional time to submit comments on the draft guidance.

DATES: Written comments by January 27, 2000.

ADDRESSES: Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Arthur K. Yellin, Center for Devices and Radiological Health (HFZ-200), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 800-638-2041, ext. 146 or 301-443-6597, ext. 146.

SUPPLEMENTARY INFORMATION:

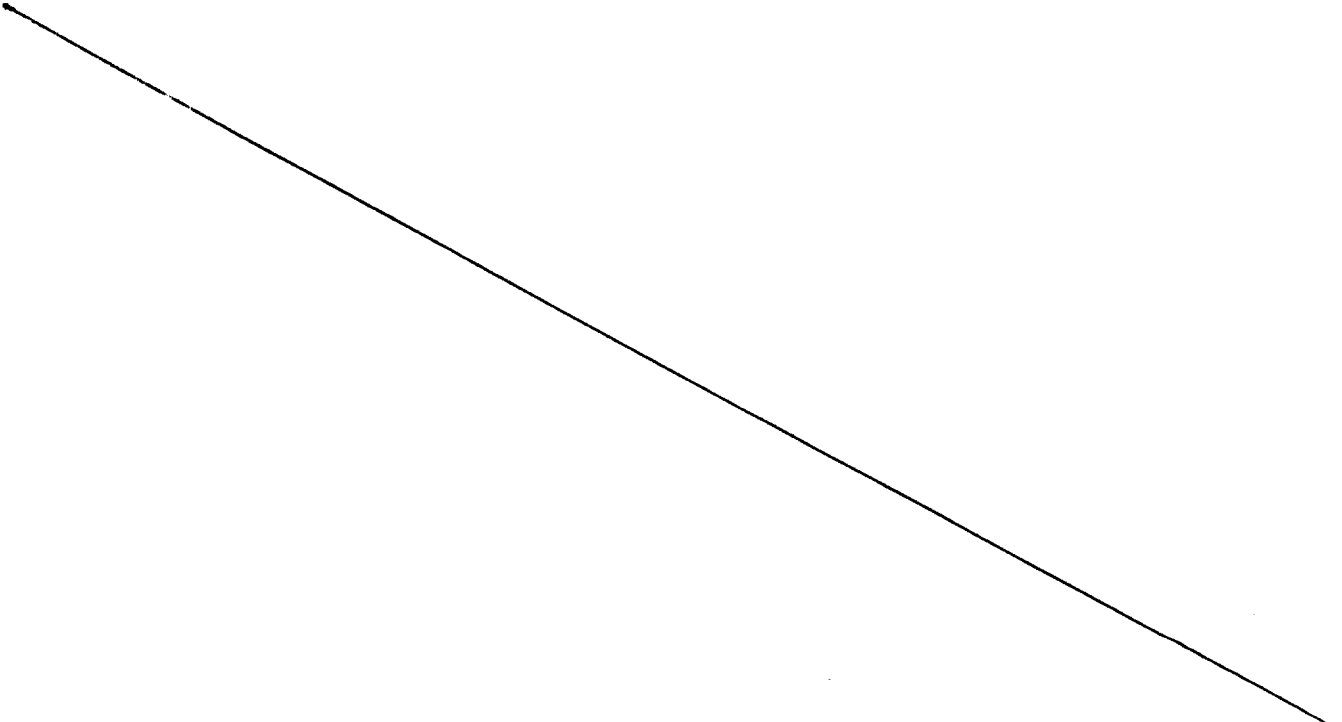
I. Extension of Comment Period

In the **Federal Register** of July 30, 1999, FDA published a notice of availability of the draft guidance entitled “Medical Glove Guidance Manual.” The draft guidance is intended to provide current information to assist manufacturers and others in obtaining marketing clearance, applying manufacturing and design controls, and properly labeling medical gloves. FDA also proposes to use the “Medical Glove Guidance Manual” as a special control in its proposed reclassification of surgeon’s and patient examination gloves (64 FR 41710 at 41714).

Elsewhere in this issue of the **Federal Register**, FDA is announcing an extension of the comment period for the proposed rule on the reclassification of surgeon’s and patient examination gloves. Because FDA has proposed that the “Medical Glove Guidance Manual” be a special control in that proposed reclassification, FDA wanted to harmonize the comment periods. Consequently, FDA is extending the comment period on the draft guidance for 90 additional days.

II. Comments

Interested persons may, on or before January 27, 2000, submit to the Dockets Management Branch (address above) written comments regarding the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to



be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 10/21/99

October 21, 1999



Margaret M. Dotzel
Acting Associate Commissioner
for Policy

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